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PTO/SB/21 (07-06)

Approved for use through 09/30/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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|   |                        |                                       |
|---|------------------------|---------------------------------------|
| <b>TRANSMITTAL FORM</b><br><br>(to be used for all correspondence after initial filing) | Application Number     | 10/621,711                            |
|   | Filing Date            | July 17, 2003                         |
|   | First Named Inventor   | Te-Yen CHIEN                          |
|   | Art Unit               | 1615                                  |
|   | Examiner Name          | Ghali, Isis A D                       |
| Total Number of Pages in This Submission  | Attorney Docket Number | 48378-0003-01-US (formerly AGIL-0043) |

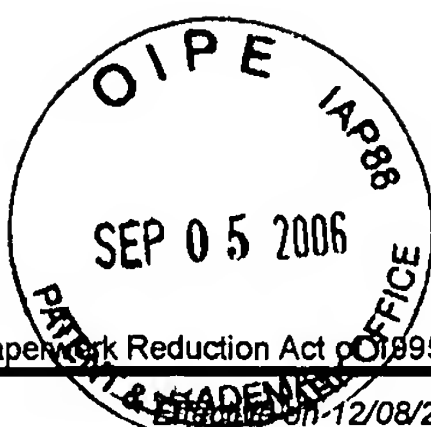
| ENCLOSURES (Check all that apply)   |  |   |
|---|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input checked="" type="checkbox"/> Fee Attached<br><br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement (Supplemental)<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><br><input type="checkbox"/> Reply to Missing Parts/Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br><input type="checkbox"/> Change of Correspondence Address<br><br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><br><input type="checkbox"/> Proprietary Information<br><br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):<br>Postcard Receipt |
| Remarks   |  |   |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT |                            |          |        |
|--|----------------------------|----------|--------|
| Firm Name                                  | DRINKER BIDDLE & REATH LLP |          |        |
| Signature                                  |                            |          |        |
| Printed name                               | JANET E. REED, Ph.D.       |          |        |
| Date                                       | 8/29/06                    | Reg. No. | 36,252 |

| CERTIFICATE OF TRANSMISSION/MAILING   |                |      |                 |
|---|----------------|------|-----------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: |                |      |                 |
| Signature   |                |      |                 |
| Typed or printed name   | Karen M. Spina | Date | August 30, 2006 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/17 (07-06)

Approved for use through 01/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).  
Effective 01-12/08/2004.**FEE TRANSMITTAL**  
**For FY 2005**☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180

**Complete if Known**

|                      |                  |
|----------------------|------------------|
| Application Number   | 10/621,711       |
| Filing Date          | July 17, 2003    |
| First Named Inventor | Te-Yen CHIEN     |
| Examiner Name        | Ghali, Isis A D  |
| Art Unit             | 1615             |
| Attorney Docket No.  | 48378-0003-01-US |

**METHOD OF PAYMENT** (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 50-0573 Deposit Account Name: \_\_\_\_\_

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17☒ Credit any overpayments**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES |                       | SEARCH FEES |                       | EXAMINATION FEES |                       | Fees Paid (\$) |
|------------------|-------------|-----------------------|-------------|-----------------------|------------------|-----------------------|----------------|
|                  | Fee (\$)    | Small Entity Fee (\$) | Fee (\$)    | Small Entity Fee (\$) | Fee (\$)         | Small Entity Fee (\$) |                |
| Utility          | 300         | 150                   | 500         | 250                   | 200              | 100                   |                |
| Design           | 200         | 100                   | 100         | 50                    | 130              | 65                    |                |
| Plant            | 200         | 100                   | 300         | 150                   | 160              | 80                    |                |
| Reissue          | 300         | 150                   | 500         | 250                   | 600              | 300                   |                |
| Provisional      | 200         | 100                   | 0           | 0                     | 0                | 0                     |                |

**2. EXCESS CLAIM FEES****Fee Description**

Each claim over 20 (including Reissues)

| Fee (\$) | Small Entity Fee (\$) |
|----------|-----------------------|
| 50       | 25                    |

Each independent claim over 3 (including Reissues)

|     |     |
|-----|-----|
| 200 | 100 |
|-----|-----|

Multiple dependent claims

|     |     |
|-----|-----|
| 360 | 180 |
|-----|-----|

| Total Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
|--------------|--------------|----------|---------------|
|--------------|--------------|----------|---------------|

- 20 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of total claims paid for, if greater than 20.

| Indep. Claims | Extra Claims | Fee (\$) | Fee Paid (\$) |
|---------------|--------------|----------|---------------|
|---------------|--------------|----------|---------------|

- 3 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of independent claims paid for, if greater than 3.

**Multiple Dependent Claims**

| Fee (\$) | Fee Paid (\$) |
|----------|---------------|
|----------|---------------|

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof | Fee (\$) | Fee Paid (\$) |
|--------------|--------------|--|----------|---------------|
| - 100 =      | / 50 =       | (round up to a whole number) x                   |          |               |

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

**Fees Paid (\$)**

Other (e.g., late filing surcharge): 37 CFR 1.17(p) submission of Information Disclosure Statement \$180

**SUBMITTED BY**

|                   |                      |  |                          |
|-------------------|----------------------|--|--------------------------|
| Signature         |                      | Registration No. (Attorney/Agent) 36,252 | Telephone (215) 988-3338 |
| Name (Print/Type) | JANET E. REED, Ph.D. |  | Date 8/29/06             |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent application of: Te-Yen CHIEN

Application No.: 10/621,711

Confirmation No: 1537

Filed: July 17, 2003

Group Art Unit: 1615

For: TRANSDERMAL HORMONE DELIVERY  
SYSTEM: COMPOSITIONS AND  
METHODS

Examiner: GHALI, Isis A D

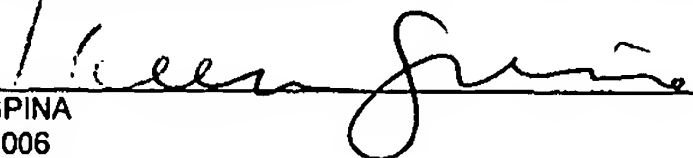
MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, the references listed on the accompanying substitute Form PTO-1449 are being identified in the above-captioned application. In accordance with the *Official Gazette* Notice of 5 August 2003 regarding 37 C.F.R. § 1.98(a)(2)(i), copies of U.S. patent references are not enclosed.

**TIME OF FILING THIS  
INFORMATION DISCLOSURE STATEMENT**

The Supplemental Information Disclosure Statement transmitted herewith is being submitted after receipt of a first office action on the merits, but before a final action or allowance. The fee of \$180 required under 37 C.F.R. § 1.97(c)(2) is enclosed. Please charge any additional fee that is due in connection with this filing, or credit any overpayment, to Deposit Account No. 50-0573. This Information Disclosure Statement is supplemental to the Information Disclosure Statements filed on December 8, 2004 and March 1, 2004.

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| BY   |  |
| DATE:  | KAREN M. SPINA<br>August 30, 2006  |

The Examiner is respectfully requested to review the cited references and make them of record in the instant application as required by M.P.E.P. § 609.

This Information Disclosure Statement should not be construed as a representation that the cited references are material or prior art, or that more relevant references do not exist.

Respectfully submitted,

Date:

8/29/06



Janet E. Reed, Ph.D.

Registration No. 36,252

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SUBSTITUTE FORM PTO-1449  
U.S. DEPARTMENT OF COMMERCE  
U.S. PATENT AND TRADEMARK OFFICE

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.  
48378-0003-01-US  
(formerly AGIL-0043)

APPLICATION NUMBER  
10/621,711

FIRST NAMED INVENTOR  
Te-Yen CHIEN

FILING DATE  
July 17, 2003

ART UNIT  
1615

### U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIALS | Cite<br>No. | DOCUMENT NUMBER                | PUBLICATION DATE<br>(MM/DD/YYYY) | NAME OF PATENTEE OR APPLICANT OF<br>CITED DOCUMENT | PAGES, COLUMNS, LINES,<br>WHERE RELEVANT<br>PASSAGES OR RELEVANT<br>FIGURES APPEAR |
|----------------------|-------------|--------------------------------|----------------------------------|--|--|
|                      |             | Number-Kind Code<br>(if known) |                                  |  |  |
|                      | A           | 6689379                        | 02/10/2004                       | BRACHT   |  |
|                      | B           | 6071531                        | 06/06/2000                       | JONA et al.  |  |
|                      | C           | 6024975                        | 02/15/2000                       | D'ANGELO et al.                                    |  |
|                      | D           | 6024974                        | 02/15/2000                       | LI   |  |
|                      | E           | 5972377                        | 10/26/1999                       | JONA et al.  |  |
|                      | F           | 5780050                        | 07/14/1998                       | JAIN et al.  |  |
|                      | G           | 5676968                        | 10/14/1997                       | LIPP et al.  |  |
|                      | H           | 5645855                        | 07/08/1997                       | LORENZ   |  |
|                      | I           | 5458885                        | 10/17/1995                       | MULLER et al.                                      |  |
|                      | J           | 5122382                        | 06/16/1992                       | GALE et al.  |  |
|                      | K           | 4906169                        | 03/06/1990                       | CHIEN et al.                                       |  |
|                      | L           | 4883669                        | 11/28/1989                       | CHIEN et al.                                       |  |
|                      | M           | 4818540                        | 04/04/1989                       | CHIEN et al.                                       |  |

### FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIALS | Cite<br>No. | FOREIGN PATENT<br>DOCUMENT                      | PUBLICATION DATE<br>(MM/DD/YYYY) | NAME OF PATENTEE OR APPLICANT OF<br>CITED DOCUMENT | PAGES, COLUMNS,<br>LINES, WHERE<br>RELEVANT PASSAGES<br>OR RELEVANT FIGURES<br>APPEAR | T |
|----------------------|-------------|---|----------------------------------|--|---|---|
|                      |             | Country Code-Number-<br>Kind Code<br>(if known) |                                  |  |   |   |
|                      |             |   |                                  |  |   |   |

### NON PATENT LITERATURE DOCUMENTS

| EXAMINER<br>INITIALS | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Publisher, city and/or country where published | T |
|----------------------|-------------|--|---|
|                      |             |  |   |
| EXAMINER SIGNATURE   |             | DATE CONSIDERED  |   |

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.